DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 1, 2015

Invictus Medical, Incorporated
c/o Mr. Scott Thiel
Navigant Consulting
9001 Wesleyan Road, Suite 200
Indianapolis, Indiana 46268

Re: K150243
Trade/Device Name: Invictus Medical, Inc. *GEL*Shield
Regulation Number: 21 CFR 880.6450
Regulation Name: Skin pressure protector
Regulatory Class: I
Product Code: FMP
Dated: January 30, 2015
Received: February 2, 2015

Dear Mr. Thiel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150243

Device Name
Invictus Medical, Inc. GelShield

Indications for Use *(Describe)*
The Invictus Medical, Inc. GelShield is a gel-filled positioning product that helps alleviate pressure caused by prolonged immobility or other conditions where frequent repositioning is contraindicated.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K150243
510(k) Summary

Submitter Information

Invictus Medical, Inc.
12500 Network Blvd.
Suite 308
San Antonio, TX 78249

Contact Person: Scott Thiel
317.228.8700
Scott.thiel@navigant.com

Date: January 30, 2015

Trade Name: Invictus Medical Inc. *GELShield*

Common Name: Skin pressure protectors

Classification Name(s): Skin pressure protectors

Classification Number: 21 CFR 880.6450 (FMP); Class I

Predicate Device

510(k) Number	Device Name	Submitter Name
K812344	Heel or Elbow Protector	Fred Sammons

Reference Device(s)

510(k) Number	Device Name	Submitter Name
K801694	Flotation Pad	Action Products, Inc.

Device Description

Invictus Medical, Inc. (Invictus) has developed the Invictus Medical, Inc. *GELShield* to reduce pressure localization on the heads of infants in Neonatal Intensive Care Units (NICU). The Invictus device is a gel-filled positioning product that helps alleviate pressure caused by prolonged immobility or other conditions where frequent repositioning is contraindicated. The product achieves this through two design characteristics: first to reduce overall friction between the outer layer of skin covering the skull and external surface; and second, to evenly redistribute external pressures over boney prominences of the skull.

The device wraps around the back of the head starting just behind the ears. It has a three dimensional curvature from foam panels that creates a curved surface of the primary outer material, Recovery5™ HF Healthcare Fabric, a low-friction material that is also used on surgical mattresses. Coupled with silicone appliques on the inner surface, the design helps the device stay in place on the head allowing the infant to move normally. This is augmented through the use of Velcro™ (as part of the device) which is used to snugly secure the device to the head. The Velcro allows the nursing staff to easily remove and re-secure the device as part of the usual care of the patient. The device also contains panels of hydrogel encased in Versaflex designed to reduce pressure localization. The Invictus Medical *GELShield* is not sterile when used. The device is single patient use, but can be worn by a given patient for multiple use periods during the patient's stay in NICU.

Intended Use(s)

The Invictus Medical, Inc. *GELShield* is a gel-filled positioning product that helps alleviate pressure caused by prolonged immobility or other conditions where frequent repositioning is contraindicated.

Technological Characteristics

Property or Characteristic	**Proposed Device** **Invictus *GelShield***	**Predicate Device (K812344)** **Heel/Elbow Protector (Sammons)**	**Reference Device (K801694)** **Flotation Pad for Operating Table (Action Products)**
Use Environment	Used in neonatal intensive care unit (NICU)	Anywhere	Used generally in operating suites

Property or Characteristic	Proposed Device Invictus *GelShield*	Predicate Device (K812344) Heel/Elbow Protector (Sammons)	Reference Device (K801694) Flotation Pad for Operating Table (Action Products)
Sterility	N/A	N/A	N/A
Conditions of Use	Disposable, single-patient use	Reusable, multi-patient use	Reusable, multi-patient use
Mechanism of Action	Utilizes low-friction material surrounding sealed containers of hydrogel to diffuse and distribute localized pressure.	Utilizes compression bandage material surrounding containers of hydrogel to diffuse and distribute localized pressure.	Utilizes low-friction material surrounding sealed containers of hydrogel to diffuse and distribute localized pressure.
Outer Material Design Features	Recovery5™ HF Healthcare Fabric Silicone stripes	Acrylic/spandex	Recovery Healthcare Fabric (various versions)
Pressure Distribution Design Features	Foam Hydrogel encased in Versaflex	Hydrogel pad	High-density foam Akton® Polymer
Closure/Attachment Design Features	Velcro strips to hold support device in place	Compression sleeve holds gel pad in place	N/A – patient lies on
In-Vitro Diagnostic device?	The product is not an *in vitro* diagnostic device	Same	Same

Non-Clinical Performance Data

Biocompatibility testing performed on the assembled devices per applicable standards within the ISO 10993 series of standards passed all testing requirements.

Pressure mapping profiles of the Invictus *GELShield* design confirmed a redistribution of pressure, reducing the potential impact of localized pressure.

Clinical Performance Data

A usability safety study was performed to assess product design and labeling use in a Neonatal Intensive Care environment. Consented subjects wore the Invictus *GELShield* over a representative period of time to assess the function of the device and associated labeling. Safety information was collected at specified time points utilizing a widely recognized dermal assessment tool, health assessments (temperature, pulse, respiration rate), and note of any excessive scalp sweating/moisture accumulation. There were no adverse events during the study.

A pre-determined dermal rating of ≤ 2 for all ratings was required for the study to pass. All rating scale data was collected and analyzed using descriptive statistics to determine overall HCP assessments of the products form, fit and performance. Dermal assessment scores and occurrence of adverse events were collected and analyzed using descriptive statistics. Any open-ended comments were captured and reviewed by the sponsor to guide future potential design changes, etc., should they be needed.

Rating data collected during the study passed the pre-determined acceptance criteria.

Non-Clinical and Clinical Performance Data Conclusions

The testing results indicate the Invictus *GELShield* is as safe and effective as the predicate device and appropriate for use with the patient population for the purpose intended.